



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-11EC]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems—New—National Center for Emerging and Zoonotic Infectious Diseases - Office of Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, drinking water distribution systems are designed to deliver safe, pressurized drinking water to our homes, hospitals, schools and businesses. However, the water distribution infrastructure is 50-100 years old in much of the U.S. and an estimated 240,000 water main breaks occur each year. Failures in the distribution system such as water main breaks, cross-connections, back-flow, and pressure fluctuations can result in potential intrusion of microbes and other contaminants that can cause health effects, including acute gastrointestinal illness (AGI) and acute respiratory illness (ARI).

Approximately 200 million cases of AGI occur in the U.S. each year, but we lack reliable data to assess how many of these cases are associated with drinking water. Further, data are even more limited on the human health risks associated with exposure to drinking water during and after the occurrence of low pressure events (such as water main breaks) in drinking water distribution systems. A study conducted in Norway from 2003-2004 found that people exposed to low pressure events in the water distribution system had a higher risk for gastrointestinal illness. A similar study is needed in the United States.

The purpose of this data collection is to conduct an epidemiologic study in the U.S. to assess whether individuals

exposed to low pressure events in the water distribution system are at an increased risk for AGI or ARI. This study would be, to our knowledge, the first U.S. study to systematically examine the association between low pressure events and AGI and ARI. Study findings will inform the Environmental Protection Agency (EPA), CDC, and other drinking water stakeholders of the potential health risks associated with low pressure events in drinking water distribution systems and whether additional measures (e.g., new standards, additional research, or policy development) are needed to reduce the risk for health effects associated with low pressure events in the drinking water distribution system.

We will conduct a cohort study among households that receive water from five water utilities across the U.S. The water systems will be geographically diverse and will include systems that use chlorine and monochloramine as secondary disinfectants. These water utilities will provide information about low pressure events that occur during the study period using a standardized form (approximately 12-13 events per utility). Utilities will provide address listings of households in areas exposed to the low pressure event and comparable households in an unexposed area to CDC staff, who will randomly select participants and send them a survey consent document and

questionnaire. After consenting to participate, the selected households will be asked to respond to questions about symptoms of AGI and acute respiratory illness (ARI) that occurred during the 3-week period following the low pressure event. Respondents will also be asked about relevant exposures during the 3-week period, such as their household water use, changes noted in their water service, international travel, children or adult household member employed at daycare, pets in the household and other animal contact, and recreational water exposure. Study participants will be able to choose among two methods of survey response: a mail-in paper survey and a web-based survey. Participation in this study will be voluntary. No financial compensation will be provided to study participants. The study duration is anticipated to last 24 months. For the multi-site study, utility personnel will provide information on each of 65 low pressure events, collect and ship water samples to the CDC, and provide line listings of affected and unaffected customers to CDC. An estimated 6,750 households will be contacted, and we anticipate 4,050 surveys will be completed and returned, providing data on 8,100 utility customers (18 years of age or older). We will conduct a pilot study of 6 low pressure events (duration approximately 3 months) prior to launching the multi-site study. An estimated 630 households will be contacted and we anticipate 756 adults (18 years of age or older) will consent to

participate in the pilot study and provide data on individuals. There are no costs to respondents other than their time. The total estimated annualized burden hours are 588.

Estimate of Annualized Burden Hours

Form Name/ Respondents	No. Respondents	No. Responses per Respondent	Average Burden per Response (in hours)
Multi-Site Study			
Web-based questionnaire - individual customers	1,215	1	12/60
Paper-based questionnaire - individual customers	810	1	12/60
Low pressure event form & samples - utility employees	5	7	45/60
Line listings - utility employees	5	7	3
Pilot Study			
Web-based questionnaire - individual customers	114	1	12/60
Paper-based questionnaire - individual customers	76	1	12/60
Low pressure event form & samples - utility employees	1	3	45/60
Line listings - utility employees	1	3	3

DATE: October 25, 2012

Ron A. Otten, Ph.D.
 Director, Office of Scientific Integrity
 (OSI)
 Office of the Associate Director for Science
 (OADS)
 Office of the Director
 Centers for Disease Control and Prevention

[FR Doc. 2012-26834 Filed 10/30/2012 at 8:45
am; Publication Date: 10/31/2012]